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NCI Seeks Health Care Provider Groups To Form Cancer Control Research Network

NCI is seeking grant applications from health care provider organizations interested in forming "research networks" for conducting cancer control studies.

The Institute released a Request for Applications last week announcing its intention to award $16.8 million over the next four years to support one or two research networks.

Though health maintenance organizations and other provider organizations can apply for regular NCI research grants, the new program is the Institute's first attempt to form a research group of relatively large

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In Brief

M.D. Anderson Selects Raphael Pollock To Lead Surgery Div.; S.F. VA Picks Norton

RAPHAEL POLLOCK was named head of the division of surgery at **M.D. Anderson Cancer Center**. Pollock will remain in his position as chairman of the department of surgical oncology, and professor of surgery and tumor biology at the center. . . . . **JEFF NORTON** was named chief of surgery at the **San Francisco Veterans Affairs Medical Center**, and professor of surgery and vice chair of of the department of surgery at the University of California San Francisco. Norton is the former associate director of the Washington University School of Medicine's Comprehensive Cancer Center, and chief of endocrine and oncologic surgery, and professor of surgery at the medical school. . . . **RONALD GOLDFARB** was named chairman of the departments of biochemistry/molecular biology and microbiology/immunology at the **University of North Texas Health Science Center at Fort Worth**. Goldfarb is the former deputy director for basic research and director of the program in cancer metastasis and cell biology at the Universtiy of Pittsburgh Cancer Institute . . . **JAMES CANCER HOSPITAL AND RESEARCH INSTITUTE** at Ohio State University was named as a site for the NCI AIDS Malignancy Consortium. The institute is one of 16 centers participating in the consortium, which is focusing studies on AIDS-related lymphomas and Kaposi'sarcoma. . . . . **JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION** plans to develop a website in collaboration with the journal **Science** that will contain a searchable database of the genetic factors of human diseases. The first two components will focus on breast cancer and Alzheimer's disease.

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Provider Organizations Sought For Cancer Control Research

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provider organizations whose primary mission is community health care.

As envisioned in the RFA, the organizations would form one or two "Cancer Research Networks," or CRNs, for collaborative research in cancer control and prevention. Networks must include enough member organizations to reach a total patient population of 2 million adults.

The RFA avoids comparing the CRNs to the NCI-funded cooperative groups, which consist primarily of academic institutions and research hospitals. One goal of the program is to raise the level of research capability in the provider organizations so they may eventually participate in research with cooperative groups and NCI-funded cancer centers, according to the RFA. The program also encourages collaboration between providers and academic researchers.

NCI's proposal to set aside research funds from the regular grant pool to help primarily for-profit provider organizations was controversial. In its first presentation to the NCI Board of Scientific Advisors earlier this year, the RFA concept was tabled. On a second try last June, the concept was approved on a vote of 14-8 (**The Cancer Letter**, July 11).

The RFA was broadened to include health care networks associated with academic institutions, as well as traditional HMOs.

The grants will be administered by staff of the Applied Research Branch in the Division of Cancer Prevention and Control. Under a reorganization of the Institute's prevention and control programs announced last July, the branch will move to the new Division of Cancer Control and Population Science on Oct. 1.

The excerpted text of the RFA follows. Contact the program director listed under Inquires for further information.

RFA CA-97-017

Title: **Cancer Research Network Across Health Care Systems**

Letter of Intent Receipt Date: Oct. 17

Application Receipt Date: Nov. 25

The purpose of this RFA is to encourage the expansion of collaborative cancer research among health care provider organizations that are oriented to community care, have access to large, stable and diverse patient populations and are able to take advantage of existing integrated data-bases that can provide patient-level information relevant to research studies on cancer control and cancer-related population studies. Health care provider organizations range from traditional staff model health maintenance organizations to extended health care networks associated with academic medical centers. A CRN would consist of a research network of such health care provider organizations that possess in-house clinical research capacity, that collaborate with other provider organizations with such capacity, or with clinical researchers affiliated with academic health centers. A CRN should consist of diverse members drawn from a number of financially autonomous and managerially distinct organizations. In this RFA, organizations which affiliate for research purposes as components of the Cancer Research Network will be referred to as CRN members.

The NCI Division of Cancer Control and Population Science invites applications for cooperative agreements to develop and support a cancer research infrastructure, consisting of one or more networks, composed of health care provider organization researchers who will be capable of conducting studies of cancer epidemiology, treatment, and prevention and control. The central objective of this RFA is to encourage cancer research uniquely well-suited to the research interests and strengths of researchers affiliated with health care provider organizations as well as of high priority to NCI. The RFA is also intended to encourage collaboration between researchers based as health care provider organizations and researchers affiliated with academic medical centers.

The CRN will be led by a Principal Investigator, a

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researcher affiliated with one of the CRN members, who will coordinate of overall activities of the CRN. Each CRN member will also be represented by a co-PI, who may also be designated as lead researcher on one or more of the specific research projects of the CRN. The organizational entity with which the CRN PI is affiliated will be the awardee institution and the lead institution for the CRN. The application must name the CRN PI, co-PI and the respective CRN organizational members.

Applications may be submitted by domestic for-profit and non-profit health care provider organizations (network members) acting jointly as a U.S. research network. A domestic application may not include an international component. Networks must include a sufficient number of health care provider organization members, such that total patient enrollment is at least 2 million adults (ages 18 and over). Network covered populations must include diverse populations with respect to gender, race/ethnicity and, to the extent that is practical, rural/urban and geographic location. Applicants must demonstrate a shared commitment among all participating network members to working together on proposed research studies. Applicants must show evidence of ability to access and organize data collection from all participating network members. Applicants are encouraged to demonstrate the capability of data linkages with local centralized tumor registries, pathology and radiologic facilities, and state vital records. If these capabilities do not currently reside within one or more of the network members, the applicant may assemble a group with plans to develop the necessary expertise across all network members. Each network member must have access to a resource unit that supports research data management locally or centrally.

The administrative and funding instrument to be used for this program will be a cooperative agreement (U19), an "assistance" mechanism in which substantial NIH scientific and/or programmatic involvement with the awardee is anticipated during performance of the activity. (The U19 is a program project cooperative agreement. Therefore, the NCI Program Project Guidelines must be used in the preparation of applications in response to this RFA). Total project period may not exceed 4 years. The anticipated award dates will be Summer 1998.

The estimated funds (total costs) available for the first year of support for this program is $4 million. It is anticipated that 1 or 2 applicants will receive awards.

Research Objectives: The purpose of this RFA is to enhance research on cancer epidemiology, prevention, early detection and control in the context of health care delivery systems. The initiative will support the development of research capabilities across multiple healthcare provider organizations for the conduct of cancer research projects. The CRN will accomplish two major objectives:

—Formulate and implement a joint CRN research agenda resulting in the conduct of three or more specified research projects in selected areas of cancer control and population studies.

—Develop standardized data collection instruments, surveys and analytical methods to promote the development of consistent and uniform data bases, and other research materials that can be shared across member institutions and utilized in joint research projects using uniform protocols when appropriate.

In accomplishing these objectives NCI anticipates the development of increased cancer research capacity through increased sharing of specific expertise, thereby raising research competence of all CRN members. This would enable more CRN based researchers to participate more fully in existing NCI-sponsored research mechanisms, such as CCOPs and Cooperative Groups and to collaborate with NCI-sponsored cancer centers.

Background: NCI has long supported a program of research in cancer control that is designed to identify promising innovations in cancer prevention, detection, treatment and rehabilitation and to demonstrate, through controlled studies, which interventions are efficacious. As cancer control research matures there is a growing need to identify existing patient care settings and existing data resources that will facilitate the conduct of cancer control translational research. Once efficacy for specific interventions has been demonstrated in selected populations, research on effectiveness in larger, more diverse populations found in representative community settings is essential to ensure the full benefit of the intervention is realized. Efficacy, which denotes how well the intended objectives of a procedure or treatment are realized in ideal settings, such as a research trial, is a necessary but not sufficient prerequisite of effectiveness. Effectiveness implies that an efficacious intervention is also feasible and can be replicated in diverse settings at reasonable economic cost. Settings that capture large, diverse care populations also constitute a valuable resource for conducting studies of primary prevention interventions, novel methods of early detection and interventions designed to increase the quality-of-life and reduce the risk of recurrent disease in cancer survivors.

In order to conduct studies of effectiveness at the national level, it is necessary to capture a large and diverse patient population with adequate representations of individuals by age, gender, income, education, minority status and urban/rural and geographical locations. Sample size requirements will vary from study to study, but many studies may require a CRN population of a few million persons. This would be true of many studies that require cancer incidence, stage-at-diagnosis, survival, or cancer patterns of care as study endpoints. For example, a health care provider organization with a membership of one million individuals over the age of 18 would expect about 750 newly diagnosed breast cancer cases each year and about 133 deaths from breast cancer. Much smaller

numbers of cases would be expected for specific sub-populations that may be of interest or for the less common cancer sites.

While historically less research-oriented than academic medical centers, some large health care provider organizations have substantial records of conducting clinical research supported by R01 grants as well as internal funds. There is currently growing interest on the part of provider organizations in participating in clinical research, and there has been rapid development and standardization, among these organizations, of integrated epidemiological-clinical-financial databases that would greatly facilitate the conduct of cancer control research on a large population-based scale. In addition, many academic health centers have developed extensive primary care networks that provide formal links between primary care delivery systems and the research capabilities of traditional academic centers.

Certain provider organizations possess characteristics that make them particularly well suited for population-based medical research. This is especially true of provider organizations that have:

—Patient populations enrolled in the provider organization over an extended period that are roughly representative of the general population, and that receive most or all of their medical care services through those organizations.

—Research resources including qualified and experienced clinical research personnel with institutional access to research-oriented primary care and specialty physicians.

—A history and/or willingness to establish collaborative research relationships with clinical research personnel affiliated with academic medical centers.

—Practice settings with an emphasis on prevention, detection and treatment of early stage disease.

—The capability to track individual patients longitudinally and, by record linkage from diverse sources, to integrate information on patient clinical characteristics with information on behavior, knowledge and attitudes, health status, and medical care use, cost and cancer outcomes.

—An organizational structure that facilitates the collection of study specific data on organization members, recruitment of members into intervention trials and demonstration projects, and the linkage of these data with existing patient-specific clinical data.

—An emphasis on the practice of evidence-based medicine, with a priority on the public health and welfare of organization members.

Objectives and Scope: Research funded by this RFA might address any of the diverse areas noted below:

—Studies which address the distribution of preventable cancer risk factors and the burden of disease in the covered population of the CRN;

—Studies which evaluate how innovative cancer prevention and control programs, based on rigorous intervention research, can be effectively disseminated throughout and implemented in the context of health care provider systems;

—Studies of the relationship between health care delivery system organizational structure and patterns of cancer prevention and control service delivery associated with access to care and favorable outcomes.

In addition, research funded by this RFA should be designed to take advantage of the large patient populations and diverse patient care settings, the integrated data systems and the other complimentary research resources made available by the CRN to achieve research objectives that would otherwise be infeasible or prohibitively expensive. Areas of research that would be particularly enhanced by this mechanism include:

Epidemiological Studies:

—Epidemiological studies in which longitudinal medical records are particularly useful in identifying cancer risk factors, including the potential risks associated with pharmaceuticals, medical devices, and other forms of non- cancer treatment.

—Studies of the long-term risk of second cancers or other late effects of cancer treatment.

Behavioral Cancer Prevention and Control:

—Studies of the feasibility, cost-effectiveness and dissemination of efficacious bio-behavioral cancer prevention and control interventions.

—Studies of innovative behavioral cancer prevention and control interventions targeted to specific populations in different organization settings, e.g., physician practice, ancillary health personnel, or public education.

—Studies of delivery systems for counseling and other approaches used for genetic testing, monitoring for cancer occurrence and preventive interventions.

Evaluation and Methodological Studies Related to Clinical Trials:

—Research on the costs and benefits to patient enrollees and health care provider institutions that result from participation in NCI or other trials. One purpose of this research is to identify strategies for increasing accrual to NCI trials.

—Methodological research on the incorporation of quality-of-life, patient satisfaction and economic endpoints in NCI trials through direct clinical trial data collection or by other methods such as using modeling or other extrapolation methods to make it possible to use retrospective data to supplement the analysis of within-trial data.

Survivorship Issues:

—Studies of indirect costs, quality-of-life, complications and recurrence as a function of treatment approach, care setting and referral patterns.

—Studies of interventions to prevent morbidity associated with cancer and its treatment

Cancer Control Surveillance and Outcomes Research:

—Studies of existing patterns of care for cancer prevention, screening, treatment, and rehabilitation in relationship to existing evidence of efficacy, cost-effectiveness, clinical recommendations and practice guidelines.

—Studies of the effectiveness of preventive medicine and evidence-based medical practice.

—Studies of the diffusion of state-of-the-art cancer prevention, screening, treatment, care and rehabilitation.

—Studies of the formulation and implementation of organizational policy regarding the dissemination of innovative technology, e.g., counseling, screening for genetic predisposition to cancer and newly approved advanced diagnostic imaging tools.

Clinical Informatic Studies:

—Studies of the feasibility, effectiveness and cost of using clinical informatic systems to identify, recruit and track organization members for targeted cancer prevention and screening interventions.

—Studies of the feasibility, effectiveness and cost of using clinical informatic systems to aid patient/physician decision making for cancer prevention, screening and treatment.

—Studies of the feasibility, effectiveness and cost of using clinical informatic systems as an aid to multi-disciplinary management of cancer care.

Special Requirements: Applications are required to describe four components: the CRN research agenda component, a research study component consisting of three or more specific research studies, an infrastructure component and an evaluation component. The research agenda component should discuss the theme of the CRN research agenda and the rational for this theme. The research study component should describe the specific collaborative studies that the CRN proposes to conduct. The infrastructure component would describe the proposed means by which the CRN would build the collaborative cancer research capacity of the network to support the proposed studies. The evaluation component should describe an evaluation study designed to determine how successful the development of the CRN has been in meeting the goals of this RFA.

The nature of health care provider organization patient enrollment for each of the CRN members must be documented. The nature of CRN member data systems must be documented.

The feasibility and willingness of CRN members to link data to a SEER cancer registry or other population-based (e.g., state cancer registries) or hospital-based tumor registries should be described. Existing linkage to cancer registries should be documented in the application.

The feasibility and willingness of CRN members to link to other types of data resources, such as registries related to cancer surveillance or genetics, health related survey data, radiology and pathology facilities data, demographic and socioeconomic data, data on use of out-of-plan services, and state vital records should be described.

Institutional research capacity and experience of each member of the CRN must be documented, including the number and qualifications of in-house research staff. All research capacity and experience related to cancer research must be documented, including collaboration with or membership in existing NCI cancer centers, cooperative groups, CCOP research bases, or consortia.

The applicant must describe how the activities of the CRN will result in the increased capacity of individual members of the CRN or the CRN as a whole to conduct research under existing NCI mechanisms.

It is recommended that the infrastructure component of the study comprise approximately one-third of the (total 4 year) budget of the CRN. The infrastructure component should be designed to meet two goals: support of the specific research studies proposed and development of the general research capacity of the CRN and its affiliated network members.

In the research component of the application the applicant CRN must describe at least three specific research studies planned for the funding period. It is recommended that the research component of the study comprise approximately two-thirds of the (total 4 year) budget of the CRN.

It is recommended that the evaluation component comprise between 2-5% of the budget of the CRN. The purpose of the evaluation component is to evaluate how well the CRN, and especially the infrastructure component, performs to meet the goals of this RFA.

The CRN need not have a centralized physical location, but it must have an identifiable Steering Committee which will work with an NCI Program Director in the context of a Cooperative Agreement.

The CRN Steering Committee will be the main governing board of the CRN and will have primary responsibility for overall policies and procedures of the CRN and for decisions about and approval of specific research protocols and pooled data analysis. The CRN PI will serve as the Chairperson of the Steering Committee.

Prospective applicants are asked to submit, by Oct. 17, 1997, a letter of intent that includes a descriptive title of the proposed research, name, address, and telephone number of the Principal Investigator, identities of other key personnel and participating institutions, and number and title of the RFA in response to which the application may be submitted.

Inquires and Letter of Intent are to be sent to: Martin Brown, Applied Research Branch, NCI, Executive Plaza North Room 313, 6130 Executive Blvd., Bethesda, MD 20892-7344, tel: 301/496-5716, fax: 301/435-3710, Rockville, MD 20852 (if express/courier service), email: mb53o@nih.gov.

Funding Opportunities:

Long-Term Survivors Subject Of New NCI Grant Program

NCI has released a Request for Applications seeking proposals for research that will lead to a decrease in the physiologic and psychological morbidity associated with long term (more than 5 years) survival after cancer treatment.

The Institute has set aside $3 million to fund 12 to 15 grant applications in response to the RFA in fiscal 1998.

The NCI Board of Scientific Advisors approved the new grant program earlier this year (**The Cancer Letter**, July 11).

Following is the excerpted text of the RFA. Copies of the complete text may be obtained by contacting the program director listed under Inquiries, or through the NIH Web site at http://www.nih.gov/grants.

RFA CA-97-018

Title: **Long-Term Cancer Survivors: Research Initiatives**

Letter of Intent Receipt Date: Oct. 24

Application Receipt Date: Nov. 25

NCI invites research grant applications to identify important areas that have an impact on long term survivors of cancer. The purpose of this RFA is to support research that will lead to a decrease in the physiologic and psychological morbidity associated with long term (more than 5 years) survival after cancer treatment by addressing specific areas that affect cancer survivors to a greater extent than members of the population at large. Questions related to the experiences of the cancer survivor encompassing both physiologic and psychological variables are to be explored and interventions to promote positive outcomes evaluated where appropriate. This initiative is expected to provide information about the incidence and scope of the effects of cancer and its treatment on survivors, the relationship of treatment to late effects and to yield new insights about measures that are appropriate to the potential problems and needs of long term survivors.

This RFA is not intended to address questions that explore differences between survivors and non-survivors that may be linked to mechanisms of disease progression or genetic predisposition.

Applications may be submitted by domestic and foreign, for-profit and non-profit organizations, public and private. Teams of applicants representing a multi-disciplinary approach to the problem identified are encouraged. Racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply as Principal Investigators. Foreign institutions are not eligible to apply for First Independent Research Support and Transition (FIRST) awards.

This RFA will use the NIH Research Project Grant (R01), the Small Grant (R03) and the FIRST (R29) award. The total project period for an application submitted in response to this RFA may not exceed 5 years. The small grant (R03) is limited to 2 years. The anticipated award date is July 1998.

The estimated funds (total costs) available for the first year of support for awards under this RFA will be $3 million. Pending receipt of a sufficient number of applications of high scientific merit, the NCI intends to fund a total of approximately 12 to 15 awards in response to this RFA in FY98.

Research Objectives: There are now approximately 10 million cancer survivors in the U.S., 7 million of whom have survived for at least 5 years. Surveillance , Epidemiology and End Results data demonstrate improvements in the 5-year relative survival rates for melanoma, breast, uterine, prostate, testicular and bladder cancer, and for Hodgkin's disease and non-Hodgkin's lymphoma, from 1974-76 to 1981-87. There has been a decline in cancer mortality in the U.S. from 1990 to 1995.

Problems facing cancer survivors are multifaceted. They include physical, emotional and social stresses arising as a result of the effects of treatment, changes in lifestyle, disruption of home and family roles, and the fear of recurrence. Physical morbidity is an issue for the cancer survivor, as are psychologic and social morbidity. Cancer survivors often live with compromise, and face potential challenges arising as a result of changes in their strength and endurance, reproductive capacity, sexuality and body image.

Cancer is a disease with both physical and psychosocial sequelae. Survivors have indicated that their concerns shift over time from illness related problems and towards societal and interpersonal issues.

There is currently no consensus as to the defined needs of cancer survivors, or the long term physiologic and/or psychologic sequelae of the disease. Research into these areas is essential to delineate the long term health outcomes of cancer survivors. It is anticipated that new collaborative teams will be formed to address the issues that range from the biological/physiologic level to the psychosocial realm. The nature of the issues suggests a multi-disciplinary approach that will generate focused methods of assessment, provide impetus for research on quality of life, explore outcomes of different approaches to follow-up and surveillance of survivors as well as inquiries into the impact on family life, insurance and employment.

Many late physiologic effects have been documented for survivors of childhood cancer. These include late effects from chemotherapy and irradiation, and the effects of multi-modal treatment including new

primary cancers, impairment of cognitive, pulmonary, cardiac, hepatic, and gonadal function, and cosmetic changes. Reviews of the existing body of literature point to an increasing number of such physiologic effects.

Areas that continue to be of particular importance to cancer survivors include: issues of quality of life and psychosocial adjustment beyond the acute period of treatment; reproduction and offspring; surveillance for the adverse sequelae of treatment and the development of new cancers; and the risk of recurrence. Knowledge of the human toll of having had, and being treated for, cancer measured in terms of quality of life, social outcomes related to jobs, insurance, social interactions is needed before interventions to lessen the negative impact or support the positive adjustment in an individual are proposed.

Research Goals: The scope of this RFA is limited to long term survivors, defined here as at least five years from completion of primary cancer therapy and currently free of disease. This RFA requests applications that will provide the information about incidence and scope of effects of cancer and its treatment on survivors, their relationship to treatment, and where appropriate, proposals to test interventions, and the timing of interventions, to reduce the late morbidity of cancer and cancer therapy and to promote as normal a life as possible for the survivor. To achieve these purposes, a descriptive phase may be included to generate hypotheses about the intervention to be tested. It is suggested that the proposals will represent multi-disciplinary approaches and multiple end points where appropriate.

Scope of Research: Examples of some pertinent areas and research topics are listed below:

—Prevalence and longitudinal incidence studies of physiologic late effects, e.g. cardiac toxicities and events, pulmonary compromise, late effects of limb sparing, minimal breast surgery and reconstructive surgery, ovarian failure, renal failure, and neurologic defects.

—Prevalence and longitudinal incidence studies of psychosocial late effects, e.g. job and insurance discrimination, sexuality, quality of life, depression, cognitive function and mentation.

—Prevalence and longitudinal studies of second cancers, including investigation of risk factors.

—Reproductive function, e.g. fertility and health of offspring.

—Economic impact, e.g. evaluation of effectiveness and cost of psychosocial and other interventions that will impact on survivorship outcomes.

—Evaluation of the effectiveness of prevention interventions to prevent sequelae, e.g. cardioprotective agents, prevention of second cancers, maintenance of fertility, early interventions during treatment to lessen negative impact of sequelae.

—Exploration of the impact of survivorship related to insurance and employment discrimination, including that related to the identification of high risk status, including genetic susceptibility.

—Studies in offspring, e.g. birth defects, delayed developmental milestones and malformation rates.

—Development and testing of diverse methodologic approaches specific to cancer survivors, e.g. instrument development, adaptation and validation of existing measures for use in special populations including culturally and ethnically diverse groups and the elderly.

—Targeted prevalence studies of specific cancer related effects on survivors to determine the need for large scale studies.

Inquiries and letter of intent should be directed to: Claudette G. Varricchio, Division of Cancer Prevention and Control, NCI, 6130 Executive Boulevard, Room 300, Bethesda, MD 20892-7340, tel: 301/496-8541, fax: 301/496-8667, e-mail: varriccc@dcpcepn.nci.nih.gov.

Food & Drug Administration:

Drug Advertising Regulations To Be Eased For TV, Radio Ads

FDA has issued a draft guidance to simplify the regulations for television and radio advertisements for prescription drugs. The proposed review will clarify the current regulations, making prescription drug advertisements easier to understand for consumers.

"By describing realistic standards for television advertising of prescription drugs, we hope to end the uncertainty which has plagued both consumers and industry about the use of this medium," said Michael Friedman, FDA lead deputy commissioner. "The FDA is committed to making sure that accurate and complete information is available to consumers."

Under the existing Food, Drug and Cosmetic Act, advertisements for prescription drugs require a summary of all side effects, contraindications, effectiveness, and major risks. Due to time constraints in television and radio advertising, most companies choose to air "reminder" ads that mention only the name of the drug without indications or claims.

The proposed regulations would allow advertisers to avoid a lengthy summary by including a statement of the drug's major risks, and instructions for consumers to access more detailed information.

The draft guidance outlines a mechanism for providing consumer access through the following components: a toll-free telephone number providing product information by mail, fax, or phone; reference to print ads or publicly available brochures

containing a summary of the product labeling; an Internet web page with access to labeling information; and a statement that pharmacists or doctors can provide additional information about the drug.

The proposed regulations are part of a larger FDA review of direct-to-consumer prescription drug promotion. The agency said a more comprehensive set of regulations is being developed.

New Drugs To Require Pediatric Labeling

In related news, FDA has proposed a rule that would require all new drugs and biologics to be labeled for pediatric use.

Drugs that are already approved and marketed would be exempt from the new regulations in most cases. Under the proposed regulations, FDA would have the authority to require additional studies for pediatric use in a drug's approved indication.

"When drug labels do not include adequate pediatric information, health care providers are forced to play a guessing game that may compromise the care of their patients," said Friedman. "Not only does this mean sick kids sometimes don't get better, but they also have the potential to get worse as a result of unexpected adverse events."

The requirement would be waived if the agency finds the product likely to be unsafe for children, if pediatric studies are impossible or highly improbable, or if reasonable efforts to develop a pediatric formulation had failed.

Both proposals are open for public comment. Written comments should be sent to the Dockets Management Branch, HFA-305, 12410 Parklawn Drive, Room 1-23, Rockville, MD 20857.

FDA proposals are available at www.fda.gov in the section marked "drugs."

NIH Notifies Grantees ROTC Rule In Effect

NIH issued the following notices to grantees, in the Sept. 5 Guide to Grants and Contracts:

—Military Recruiting and Reserve Officer Training Corps Program Access to Institutions of Higher Education. Effective March 29, 1997, the Department of Defense adopted an interim rule to implement Section 514 of the Omnibus Consolidated Appropriations Act of 1997.

The rule prohibits NIH from providing funds to educational institutions that have a policy or practice (regardless of when implemented) that either prohibits, or in effect prevents (1) the maintaining, establishing, or operation of a unit of the Senior Reserve Officer Training Corps at the covered education entity; or (2) a student at the covered educational entity from enrolling in a unit of the Senior Reserve Officer Training Corps at another institution of higher education.

Under the same rule, NIH is prohibited from providing funds to educational institutions that have a policy or practice that prohibits or prevents (1) entry to campuses, or access to students (who are 17 years of age or older) on campuses, for purposes of Federal military recruiting; or (2) access by military recruiters for purposes of Federal military recruiting to information pertaining to students (who are 17 years of age or older) enrolled at the covered educational entity.

The adopted rule implements the law, and is effective March 29, 1997. Additional information can be found at gopher://gopher.legislate.com:70/11/regs/590/590178.

—Implementation of the President's Welfare-to-Work Initiative for Federal Grant Employees. On March 8, 1997, the President issued a memorandum to the heads of the executive departments and agencies entitled "Government Employment for Welfare Recipients." This memorandum directs all Federal agencies to hire people off the welfare rolls into available job positions in the government. To supplement this initiative, Federal agencies have been asked to encourage all grantees to hire welfare recipients and to provide additional training and/or mentoring to hired welfare recipients.

Additional information can be found at http://www.whitehouse.gov/WH/EOP/OMB/html/fedreg/omb-not.html.

Program Announcement

PA 97-105

Title: **HIV Pathogenesis in Women's Interagency HIV Study**

The National Institute of Allergy and Infectious Diseases, NCI, and several other NIH components including the Office of Research on Women's Health, invite applications for studies on HIV Pathogenesis in the Women's Interagency HIV Study (WIHS).

Contact Sandra Melnick, NCI, tel: 301/435-4914 fax: 301/402-4279, email: sm33k@nih.gov.